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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|----------------------|---------------------------------|------------------------|
| 10/765,725 | 01/26/2004 | Michael J. Drews | ARB-9014 | 2546 |
| 23410 | 7590 | 07/18/2007 | | |
| Vista IP Law Group LLP 2040 MAIN STREET, 9TH FLOOR IRVINE, CA 92614 | | | EXAMINER PELLEGRINO, BRIAN E | |
| | | | ART UNIT 3738 | PAPER NUMBER |
| | | | MAIL DATE 07/18/2007 | DELIVERY MODE PAPER |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/765,725

Applicant(s)

DREWS ET AL.

Examiner

Brian E. Pellegrino

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 April 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-22 and 36-53 is/are pending in the application.
- 4a) Of the above claim(s) 3 and 45 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2,4-22,36-44 and 46-53 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____

DETAILED ACTION

Claim Rejections - 35 USC § 102

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1,2,4,9 are rejected under 35 U.S.C. 102(e) as being anticipated by Yencho et al. (6776785). Fig. 11 shows a vascular assembly with a first base member **88** with a multi-lobular shape within a plane and a second annular body **88** above also having a multi-lobular shape complementary to the base. It can also be seen there is a plurality of connector elements spaced apart along the perimeter on both the base and upper body that are joined by a curve. It can be construed also that elements **90** are connecting members and a fully capable of connecting with a valve member. Please note the intended use carries no weight in the absence of any distinguishing structure.

^{44,46,47 3P 4/11/07}
Claims 1,2,4,5,7-10,36-41,43,47,49,52-55 are rejected under 35 U.S.C. 102(b) as being anticipated by Lane (6371983). Fig. 1 shows a heart valve assembly comprising an annular body **13** with a multi-lobular shape and containing multiple valve members or leaflets **15a,15b,15c**. Additionally there is a flexible cuff **17** attached to the base also comprising a multi-lobular shape. Fig. 3 illustrates that the outer frame or base member **25** has the cuff **17** attached thereto. It can be construed that since the base member is made of metal or plastic (col. 4, lines 8,9) it is rigid. As seen in Fig. 1 there is a plurality of connectors (3) spaced along the perimeter of the base member. Fig. 4 shows one of the connectors is a protrusion or pin **23** and the complementary

connector is an aperture to receive the pin. Fig. 5 illustrates the second connecting member has apertures in the form of holes **26**. Since the slots or holes are oblong it can be construed that it permits sliding of the guide members **23** in the guide channels **26**. Lane discloses that the connectors are used to fasten the base member to the annular member or valve frame, col. 3, line 67, col. 4, lines 1-5,33,34,43,44. Lane also discloses that the multiple strips are used as guides or alignment markers to affix the base and annular body together, col. 4, lines 39-42,49-52.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lane '983 in view of Griffin et al. (6241765). Lane is explained supra. However, Lane fails to disclose the pin is resilient. Griffin et al. teach (Fig. 7) a resilient pin **91** for use with a heart valve prosthesis, col. 5, lines 24,25. It would have been obvious to one of ordinary skill in the art to utilize a flexible pin as taught by Griffin et al. with the prosthesis of Lane such that it easily is inserted in the valve assembly without much force that would move the prosthesis during insertion.

Claims 11-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schreck (6454799) in view of Otto et al. (DE 19532973). Schreck discloses a base **40** with guides **42** on the base for aligning with separate annular body **22**. Schreck discloses the base is formed of a cuff like material, col. 6, lines 54-56. Fig. 2 shows the

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annular body forming valve members **32**. It can be seen (Fig. 1) that the annular body has a seam **36** and the base has guides that taper to a smaller width at which location is where the assembled valve would be considered together as shown in Fig. 2. A connector **76** is used in connecting portion **70** of annular body of which is connected to the base via connector portion **54**. It can be construed that the connector **76** provides a tactile marker since the connector slides into to the receptacle of the annular body and then abuts the ledge of the guide, see Fig. 3. However, Schreck fails to disclose the bodies of the prosthesis are of a multi-lobular shape. Otto et al. teach (figs. 1,2) that the prosthesis is designed with a multi-lobular shape to correspond to the anatomy in which it is placed, see abstract and translation of Fig. 1. It would have been obvious to one of ordinary skill in the art to use a multi-lobular shape as taught by Otto et al. for the components of Schreck's valve prosthesis such that it more closely matches the anatomical location to which it is implanted in.

Claims 18,21,22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schreck '799 in view of Otto et al. (DE 19532973) as applied to claim 11 above, and further in view of Lane '983. Schreck in view of Otto et al. is explained above. However, Schreck as modified by Otto fail to disclose the use of tethers. Lane teaches that in some heart valve assemblies a tether can be used to align the annular body with the base member, col. 7, lines 60-67.

Claims 19,20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schreck '799 in view of Otto et al. (DE 19532973) and Lane '983 as applied to claim 18

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above, and further in view of Macoviak (6893459). Schreck as modified by Otto and Lane is explained supra. However, Schreck in view of Lane and Otto fail to teach a ratchet mechanism for aligning the annular body with the base member. Macoviak teaches (Figs. 3,4) that one of the base member or annular body has a guide member **67** and the other component has ratchets **43** and the guide member in a guide channel **77**. Macoviak also teaches that the ratcheting provides the surgeon the ability with controlled placement of the valve member at the annulus, col. 6, lines 20-31.

Claims 42,48,51,51 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lane '983 in view of Macoviak (6893459). Lane is explained as before. However, Lane fails to disclose the use of a ratchet mechanism for aligning the annular body with the base member. Macoviak is explained supra. It would have been obvious to one of ordinary skill in the art to utilize a ratcheting system as taught by Macoviak with the prosthesis of Lane such that it enables the heart valve implant to be manipulated into the proper position at the implantation site. Regarding claim 48, it can be construed that the portion of the guide member that extends into the guide channel has a rectangular cross-section.

Response to Arguments

Applicant's arguments filed 4/23/07 have been fully considered but they are not persuasive. Applicant alleges that the Yencho device does not comprise a multiple component system or a separate annular body. However, it is clear from Fig. 11 of Yencho that the base and annular member are separate joined by connectors that are

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attached perpendicularly. It has been held that a recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus satisfying the claimed structural limitations. *Ex parte Masham*, 2 USPQ2d 1647 (1987). Thus, how the components are used is irrelevant since there is no distinguishing structure.

Regarding the comments about the Lane '983 rejection, the Applicant argues that the prosthetic valve of Lane is not a multiple component implant and that the inner member cannot be an annular body. However, it is the Examiner's position that since the language of the claims use "comprising" the laminates assembled together in Lane's device as noted by the Applicant together form an annular body. Applicant also argues that the amended claims 1 and 11 now reciting the annular body to be separate from the base member is not evident in Lane's device. However, the comments on page 13 and 14 of the Applicant's response stating that the components of Lane's device are attached together contradict or nullify this argument that the annular body and base member are not separate. If one object is said to be attached to another object, then they must be separate components. In response to applicant's argument that Lane's prosthetic valve components are not connected "after the base member has been introduced into a tissue annulus", a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian E. Pellegrino whose telephone number is 571-272-4756. The examiner can normally be reached on M-Fr (7:30am-5pm).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on 571-272-4754. The fax phone

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number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



BRIAN E. PELLEGRINO
PRIMARY EXAMINER